TEXAS HOSPITAL ASSOCIATION

August 26, 1999

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: FDA Draft Document Concerning the HCV Lookback Program (Document No. 99D-1878, Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components)

Ladies and Gentlemen:

On behalf of the 454 institutional members of the Texas Hospital Association, I am writing to provide comments regarding the draft guidance of the Food and Drug Administration concerning the Hepatitis C Lookback Program. The FDA guidance requires bloodbanks to notify hospitals that have been supplied with blood that may be contaminated with HCV, and hospitals in turn **must** attempt to notify blood recipients of the potential contamination and of the need for HCV testing and counseling.

The draft guidance would update the 1998 guidance in several ways. Of greatest concern to THA is the language in the draft guidance (replacing the 1998 guidance) which includes an indefinite lookback period. We agree with the American Hospital Association's position that this recommendation is vague and overly broad, and **could** place tremendous administrative and legal burdens on hospitals. THA recommends that the language be modified by striking "extend back indefinitely," and simply providing that the record search should extend back a finite and reasonable period, such as 10 years.

THA also is concerned about the high rate of false-positive results associated with the current test. According to information from the AHA, the rate of false-positive results from the EIA 1 .O test is as high as 30-70 percent. The FDA should evaluate the results of the current lookback program and document its benefits before proceeding with an expansion.

I appreciate the opportunity to provide these comments. Please call me at (5 12) 465-l 538 if you have questions.

Sincerely,

Matthew T. Wall

Matthew T. Wall
Associate General Counsel

99D-1878

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